In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-2169V

(not to be published)

* *

MARY MORENO,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES

Respondent.

* *

Chief Special Master Corcoran

Dated: January 3, 2023

Reissued for Public Availability: January 31, 2023

Mary Moreno, San Diego, CA, *pro se*, for Petitioner.

Tyler King, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DISMISSING PETITION[1]

Pro se Petitioner Mary Moreno initiated this case on November 15, 2021, seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] Petition (ECF No. 1) ("Pet.") at 1. Petitioner's initial filing alleges the causation-in-fact claim that

[1] Although this Decision has been formally designated "not to be published," it will nevertheless be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). This means that the Decision will be available to anyone with access to the internet. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id.*

Pursuant to Vaccine Rule 18(b), this Decision was initially filed on January 3, 2023, and the parties were afforded 14 days to propose redactions. The parties did not propose any redactions. Accordingly, this Decision is reissued in its original form for posting on the court's website.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

she developed viral arthropathy, arthralgia, joint pain, joint swelling, rash, hives, urticaria, fatigue, hemoptysis, right flank pain, eczema, and dermatitis after receipt of the Hepatitis B, measles-mumps-rubella ("MMR"), Fluzone Quadrivalent ("flu"), and Adacel ("Tdap") vaccines on November 12, 2018, and November 16, 2018. Pet. at 1. Petitioner subsequently clarified her injury to be eczema and eczema-related complications of hand dermatitis and blepharitis. Petitioner's Brief, dated July 28, 2022 (ECF No. 21) ("Br.").

Respondent's Rule 4(c) Report (filed on April 1, 2022) had argued that the Petition should be dismissed because Petitioner had not offered sufficient reliable evidence to establish a causal relationship with the vaccines at issue. ECF No. 17. I therefore set a deadline for Ms. Moreno to file an expert report or whatever else she deemed sufficient to substantiate her claim. Order, dated April 27, 2022 (ECF No. 19). In response, she filed a brief arguing that the medical record, coupled with existing "package insert" information about the expected side-effects of the relevant vaccines, was enough to prevail on entitlement. *See generally* Br. Respondent filed an Opposition Brief providing more specific argument for why Petitioner's claim be dismissed. Response Brief, dated Sept. 30, 2022 (ECF No. 28) ("Opp."). Respondent's motion is now ripe for resolution.

I. Brief Factual Summary

On November 12, 2018, Ms. Moreno received the Hepatitis B, flu, and Tdap vaccines in her left deltoid muscle, and then an MMR vaccine in the same place on November 16, 2018. Ex. 4 at 1. Almost three weeks later (and with no intervening medical evidence of a reaction), she went to an urgent care facility on December 2, 2018, complaining of a two-day history of joint pain in her hands, knees, and ankles, plus hives beginning in late November. Ex. 5 at 4-6. Dr. Jeffrey Sugar noted petitioner had tenderness to palpation of the wrists and hands, as well as swelling, and a skin exam showed some scattered macular erythematous lesions. *Id.* at 5. A blood test for rheumatoid factor (RF) (a recognized biomarker for rheumatoid arthritis), however, revealed normal results. *Id.* at 21. Petitioner was diagnosed with hives/joint pain of unclear etiology. *Id.* at 14.

The next day (December 3, 2018) Ms. Moreno presented to internist Dr. Sabrina Falquier for follow up. Ex. 6 at 90-92. Petitioner now reported "itchy spots" around Thanksgiving, followed by hives the week after plus novel joint pain and swelling in her hands, noting also her receipt of the MMR vaccine in mid-November. *Id.* at 90. Petitioner's physical exam was normal, however, with evidence of full range of motion, and no erythema or swelling observed. *Id.* at 91-92. Conservative treatments were therefore proposed. *Id.* at 91.

Later that same December, a blood test performed on Petitioner revealed potential biomarkers for an autoimmune condition. Ex. 5 at 22. She subsequently had a rheumatology consultation. Ex. 7 at 4-5. It was observed that her joint pain and swelling symptoms had improved (or were nonexistent), and she displayed no rash, although Petitioner reported pain in her arm and

difficulties opening packages, bottles, and jars. *Id.* She also mentioned a family history of autoimmune disease. *Id.* Petitioner's physical examination was again largely normal, and the blood test result was deemed consistent with her reported preexisting hypothyroidism. Ex. 7 at 9. Subsequent follow-up testing produced no notable findings. *Id.*

By January 2019, Petitioner began seeking treatment for a new symptom: blood in her sputum upon waking and clearing her throat. Ex. 5 at 8-10. She was initially diagnosed with hemoptysis[3] and blood-tinged sputum of an unclear etiology. *Id.* at 10. She informed one specialist treater that she had noticed this condition in late-December 2018. Ex. 8 at 7-11. He physical exam and blood testing again produced normal results, however, and did not show any signs of blood loss or a bleeding disorder. Ex. 9 at 12-18. Subsequent CT scans also resulted in normal findings. Ex. 6 at 21-22; Pet. Ex. 8 at 21.

In the middle of January 2019, Petitioner's primary care physician evaluated her, noting that her prior complaints of joint pain or a rash appeared to have resolved. Ex. 6 at 67-69. At most, he noted a temporal association with the MMR vaccine, deeming it potentially related. *Id.* He also opined that the blood in her cough could be the result of an overlooked source in her nasopharyngeal airway. *Id.* at 68-69. However, a subsequent consultation revealed no ear/nose/throat issues. Ex. 8 at 4-6. And a dermatologist found nothing abnormal and recommended against a skin biopsy for the time being (given the absence of any rash). Ex. 6 at 63-64.

Petitioner thereafter continued to seek treatment for her hemoptysis. Ex. 6 at 58-60 and Ex. 9 at 4-6 (January 29, 2019 pulmonology evaluation). But she reported at this time it had ceased the week before. Ex. 6 at 60. Petitioner's autoimmune workup was negative, and she was advised to return for further evaluation of hemoptysis if it recurred. *Id.* She also obtained additional dermatologic treatment in February 2019, but was diagnosed with eczematous dermatitis. Ex. 6 at 20, 56-57; Ex. 10 at 4-5. And the rash examined at the time was not deemed consistent with an urticarial, vasculitis, or lupus origin. Ex. 6 at 20.

For the remainder of 2019, Petitioner sought treatment for (among other things) purported right flank pain (which she later claimed migrated to her lower abdomen) beginning in December 2018(*see* e.g., Ex. 5 at 11-13, 18-23), but exams and testing confirmed no significant issues. Records from treatments obtained in 2020 do not document additional similar complaints. *See,* e.g., Ex. 14 at 9-10 (May 2020 treatment). In 2021, she reported to a treater that a biopsy obtained in February 2019 supported the diagnosis of "eczema/allergic dermatitis." Ex. 11 at 5. However, no rash was observed at that time. Records from subsequent treatment are unilluminating as to the strength or nature of Petitioner's claim.

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[3] Hemoptysis is defined as "the expectoration of blood or blood-stained sputum." *Dorland's Illustrated Medical Dictionary* 832 (33rd ed. 2020).

II. Parties' Arguments

Petitioner maintains that the vaccines she received in November 2018 caused an "adverse drug reaction," resulting in atopic dermatitis and or "eczema-related complications." Br. at 1. To support her claim, however (and despite due opportunity) she has not offered an expert report that would show how any of the relevant vaccines could have caused her injury. Instead, she details her medical history, adding two general points: (a) that the relevant vaccine "package inserts" disclose the possibility of rash/urticaria/eczema as an adverse event (*see,* e.g., *Id.* at 1-2 (Hep B vaccine), 5-7 (MMR vaccine), and 10-12 (flu and Tdap vaccines)), and (b) that other petitioners have received compensation for claims involving the same vaccines and alleged injuries (*Id.* at 17). She thus maintains she has carried her preponderant burden of proof. *Id.* at 18.

Respondent in reaction offered a brief expanding on his arguments first set forth in his Rule 4(c) Report for why the claim was appropriately dismissed. *See generally* Opp. at 3-12. Noting that the facts of this case are not consistent with any enumerated Table claims, he maintains that Petitioner cannot establish causation-in-fact. *Id.* at 4-5. First, Respondent contends Petitioner has not offered sufficient reliable evidence to establish that any of the four vaccines at issue "can cause" the kinds of dermatologic injuries alleged. *Id.* at 9. Indeed, he notes that a recitation of Petitioner's history plus reference to the package inserts does not amount to a causal theory. *Id.* at 9-10. Second, he argues that the record itself does not allow the conclusion that the vaccines "did cause" any longer-lasting eczema, regardless of whether any post-MMR transient rash was a short-lived but self-limiting vaccine adverse event, emphasizing the lack of treater support. *Id.* at 10-11. Finally, Respondent questions whether Petitioner has demonstrated an associative timeframe between the vaccinations and onset of dermatologic issues, noting that the record only suggests problems temporally arose after – not that the time in which they did was medically acceptable. *Id.* at 11-12.

Analysis

Although the record in this case does suggest Petitioner experienced *some* kind of post-vaccination rash and/or pain, it does not appear she would be able to substantiate a causation-in-fact claim[4] based on the vaccines received, based on the Federal Circuit's standard for causation-in-fact claims set forth in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

[4] Petitioner has not asserted a viable Table claim,

In particular, Petitioner is unlikely to be able to set forth a "reputable medical theory" demonstrating that the vaccines in question *can cause* the injuries alleged. *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006); *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994) (petitioner's theory must be based on a "sound and reliable medical or scientific explanation"). Rather than seek expert assistance, Petitioner has endeavored to substantiate the claim by offering other evidence – and certainly expert input is not mandated to prove Vaccine Program entitlement. But what she *has* offered is inadequate to prove that any of the four vaccines she received can cause the kind of dermatitis or eczema alleged.

First, as Respondent correctly observes, package insert disclosures about potential transient vaccine side effects are not in the Vaccine Program considered good proof of causation. *See Sullivan v. Sec'y of Health & Hum. Servs.*, No. 10-398V, 2015 WL 1404957 (Fed. Cl. Spec. Mstr. Feb. 13, 2015) ("[s]tatements contained in vaccine package inserts do not constitute reliable proof of causation, and cannot be deemed admissions that the vaccines in question have the capacity to harm a particular petitioner in a specific manner. *See Werderitsh v. Sec'y of Health & Human Servs.*, No. 99–319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) (quoting 21 C.F.R. § 600.80(l) as saying "[a] report or information submitted by a licensed manufacturer ... does not necessarily reflect a conclusion by the licensed manufacturer or FDA that the report or information constitutes an admission that the biological product caused or contributed to an adverse effect"). Second, the fact that comparable injuries have succeeded does not direct or control the outcome of this case. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). Thus, absent some reason to find in *this case* that the vaccines could cause the alleged injury, prior cases are not determinative – and Petitioner has not offered a reputable theory substantiated by any other reliable independent evidence.

In addition, Petitioner's showing is not likely to satisfy the second, "did cause" prong of the *Althen* test. Other than the temporal relationship between vaccination and onset of purported rash, nothing in the record provides a reliable basis for connecting the two. There is also no treater support for an association (beyond some speculation that Petitioner's presenting symptoms – which later resolved – might have had some transient vaccine association). And this raises a third issue with the claim (and one not set forth by Respondent): whether Petitioner would be able to demonstrate six months of severity. *See* 11(c)(1)(D)(i). For, as noted above, any skin reaction that could even be considered an actual vaccine reaction (first observed in November 2018) had likely resolved by no later than *February 2019* – and the symptoms for which she sought treatment thereafter are either uncorroborated by the record or have not been shown to be likely associated with her initial purported reaction. Again, an expert arguably *might* have been able to make a connection, but no such evidentiary support has been provided.

I am aware that dismissal of a case is a difficult consequence to bear – especially for a *pro*

se litigant. But my review of the existing record does not suggest this claim is viable, and even after being provided the chance to show why the claim should be permitted to go forward, Petitioner has not done so.

Conclusion

Under the Vaccine Act, a petitioner may not receive a Vaccine Program award based solely on her claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1). In this case, there is insufficient evidence in the record for Petitioner to meet her burden of proof, and Petitioner has not offered expert support for her causation claim. Therefore, Petitioner's claim cannot succeed and must be dismissed. Section 11(c)(1)(A).

Accordingly, I hereby **DISMISS** Petitioner's case. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[5]

IT IS SO ORDERED.

Brian H. Corcoran
Chief Special Master

[5] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.